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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/833,245	04/12/2001	Craig A. Rosen	6832.0018-00	3724
22852	7590	02/13/2004	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 1300 I STREET, NW WASHINGTON, DC 20005			BORIN, MICHAEL L	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/833,245

Applicant(s)

ROSEN ET AL.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 5-12 and 21-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-4 and 13-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

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## **DETAILED ACTION**

### ***Status of Claims***

Response to restriction requirement filed 11/25/2003 is acknowledged. Applicant elected, with traverse, Group I, claims 1-4, 13-20, drawn to conjugates of albumin or fragments thereof. In regard to Groups I and II applicant argues that claim 1 encompasses not only consecutive connection of albumin and therapeutic protein, but also insertion of protein into albumin. Examiner disagrees. There is no indication of the latter fusion proteins wherein protein is inserted into albumin; had it been there, it would have been restricted similarly to Groups I and II. Contrary, parts f,g,h,j,k of claims 1 which applicant did not cite in the traverse, are all drawn, specifically, to fused proteins wherein terminal of protein is connected to a terminal of albumin. Examiner maintains that the products of Group I and II possess distinctly different structures which will require different sequence and literature searches. In regard to Group III, Examiner apologizes for inadvertent error in claims belonging to the Group - Group III includes claim 21, not claims 19-37 as indicated in the restriction requirement. As to the grouping of claims, Examiner maintains that products of Groups I,II are capable of use separate from being used in a kit. The restriction requirement is still deemed proper and is therefore made FINAL. Claims 5-12, 21-29

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are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected groups. Cancellation of claims 5-12, 21-29 is requested.

As per election of species, applicant elected, with traverse, full-length albumin (SEQ ID No. 18). Applicant did not provide evidence that the species are obvious variants of each other and thus should be examined together. Thus, conjugates of full-length albumin are examined for initial examination on merits; other species will be addressed if and when the elected species are determined to be allowable.

Claims 1-4, 13-20 are addressed to the extent they read on conjugates of full-length albumin and a therapeutic protein or variant or fragment thereof.

#### ***Incorporation by reference***

It is noticed that applicant incorporates by reference the entire content of more than 900 patent application (pages 513-533 of specification). In view of election of Group I, claims 1-4, 13-20, drawn to conjugates of albumin, applicant is requested to provide a list of the applications from the above list that are related to the elected subject matter.

Further, as applicant does not specify that the information in the cited exhaustive list of references is essential, it is deemed to refer to non-essential subject matter.

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Furthermore, applicant's attention is directed to MPEP 608.01(p) which instructs:

Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). In addition to other requirements for an application, the referencing application should include an identification of the referenced patent, application, or publication. Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found.

### ***Sequence Listing***

The Sequence Listing filed 04/12/2001 was approved by STIC for matters of form.

### ***Claim Objections***

Claims 14-18 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form.

### ***Claim Rejections - 35 USC § 102 and 103.***

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4,13-20 are rejected under 35 U.S.C. 102(b) as anticipated by Ballance et al (WO 9724445) or Yeh et al (US 5665863) or Becquart et al (WO 95/30759) or Becquart et al (EP 413622 or US 6165470)

The instant claims are drawn to conjugates of a protein or fragments thereof connected to albumin. There are numerous publications in prior art teaching that conjugating of therapeutic proteins to albumin increases their stability and/or activity. The following references are exemplary.

Ballance et al ( WO 9724445) teaches fusion proteins of albumin and growth hormone, or fusions of variants of either, that are secreted by yeast and have increased serum and storage stability. The two domains of the fusion protein may be linked by a peptide cleavable by an endogenous proteinase.

Yeh et al (US 5665863) teaches fragments of G-CSF that are conjugated with albumin to increase their stability.

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Becquart et al (WO 95/30759) teaches biologically active polypeptides that have the biological active domains of a protein inserted into an albumin. The fusion proteins are manufactured for use as pharmaceuticals. The integration of the biological active domains into the albumin structure is particularly advantageous when the protein of interest is too fragile to be used on its own. The proteins are manufactured by expression of a chimeric gene encoding it. Preferred sites for integration of the peptide into the serum albumin framework are identified from the structure of human serum albumin.

Becquart et al (EP 413622 or US 6165470) teaches albumin-viral receptor fusion proteins are produced by recombinant cells. A plasmid encoding an albumin-CD4 fragment fusion protein was constructed. *Kluyveromyces lactis* transformed with this plasmid produced the fusion protein which was purified and characterized. The protein inhibited binding of HIV-1 to CE713 cells somewhat better than did intact CD4 and thereby reduced HIV-1 to CE713 infectivity. The half-life of this fusion protein in rabbit blood was 34 h (relative to 0.23 h for CD4 and 47 h for albumin itself).

In regard to functional limitations of claims 2-4, when the reference discloses all the limitations of a claim except a particular property or function, and the examiner cannot determine whether or not the reference inherently possesses the properties

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which anticipate or render obvious the claimed invention, the burden of proof shifts to applicant. In re Fitzgerald et al. 619 F.2d 67, 205 USPQ 594, (CCPA 1980). Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art.

In regard to claims 14-18, the limitations of the claims are not further limiting (see objection to the claims above) and do not distinguish the products as claimed.

It is the Examiners position that all the elements of Applicant's invention with respect to the specified claims are instantly disclosed by the teaching of the references cited above.

***Conclusion.***

No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are



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unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0549.

February 3, 2004

MICHAEL BORIN, PH.D  
PRIMARY EXAMINER

mlb

A handwritten signature in black ink, appearing to read 'Michael Borin', is written over the printed name and title.